Response to Office Communication dated April 19, 2005

## REMARKS

Applicants wish to thank the Examiner for the withdrawal of his objections under 37 CFR 1.75; the rejections of claims 1, 3, 7-10, 14, 15, 17-20, 22-27, 29-31, 38, 41, and 42 under 35 U.S.C. 112, first and second paragraphs; and the rejections of claims 1, 3, 7-10, 14, 15, 17-20, 22-24, 29-31, 38 and 42, under 37 U.S.C. 102(a) as being anticipated by Olek et al.

Further, Applicants wish to thank the Examiner and his SPE for courtesies extended during the in person/telephonic interview of April 27, 2005. During the interview, the claim rejections in the Office Communication of April 19, 2005, were discussed and the claim amendments herein generally suggested.

Without prejudice or disclaimer, independent claim 1 is herein amended to recite "specific identity," from blood sample of patients," and "wherein the specific identity of said more than 15 markers is not known." Support for the amendments can be found in the specification and original claims, as follows. Support for not knowing "specific identity" can be found, e.g., at pages 2-3, paragraph 0006, of the specification, which provides "without regard to the specific identity ..." and at page 4, paragraph 0013, which provides "it is not necessary to specifically identify all of the polypeptides indicated by the assay." "[F]rom blood samples of patients" finds support, e.g., at page 5, paragraph 0016, which provides "identifying patterns in blood or other patient samples," as well as at page 12, paragraph 0041, which provides "Samples collected are preferably bodily fluids such as blood ...."

Thus, there is no issue of new matter with respect to the current claim 1 amendments.

Without prejudice or disclaimer, dependent claims 17-20 are also amended to recite "<u>specific</u> identity." These amendments find support in the specification as indicated above, and also present no issue of new matter.

With the entry of these amendments, claims 1, 3, 7-10, 14-15, 17-20, 22-27, 29-31, 38, 41, and 42 are currently under examination. Applicants earnestly request reconsideration and allowance of the pending claims under examination.

## Rejections Under 35 U.S.C. §103(a)

Claims 1, 3, 7-10, 14, 15, 17-20, 22-27, 29-31, 38, 41, and 42 were rejected under 35 U.S.C. 103(a) as being unpatentable over Olek et al. with reference to Chambers et al., and in

Response to Office Communication dated April 19, 2005

view of Fouillet et al. Action at pages 3-7. Applicants respectfully submit that the alleged combination does not render the claims obvious, as detailed below.

## Obvious rejection of claim 1 should be withdrawn as the Olek-Chambers-Fouillet references fail to teach or suggest more than one limitation of the claim

Claim 1 is rejected as obvious over Olek with reference to Chambers and in view of Fouillet. Action at pages 4-5. Applicants respectfully submit, however, that there is no prima facie case of obviousness because neither Olek, nor Chambers, nor Fouillet teaches or suggests a limitation of amended claim 1. M.P.E.P. 2142. Indeed, the Olek, Chambers and Fouillet references fail to teach or suggest at least three limitations of amended claim 1.

As acknowledged with the Office's withdrawal of its prior 102(a) rejections, the Olek reference fails to disclose the limitations of "without regard to a specific identity of at least some of said mass spectral components;" "the identity of a plurality of said more than 15 markers is not known;" and "in a computer system identifying the differences in case samples and control samples using said plurality of said more than 15 markers." Similarly, the Olek reference fails to disclose limitations of currently amended claim 1 such as "without regard to a specific identity of at least some of said mass spectral components;" "the specific identity of said more than 15 markers is not known;" and "from blood samples of patients, in a computer system identifying the differences in case samples and control samples using said more than 15 markers wherein the specific identity of said more than 15 markers is not known."

Neither Fouillet nor Chambers cures these deficiencies, either alone, in combination with each other, or in combination with Olek. Fouillet provides microfluidic devices having thermal transfer members that cycle between two or more temperatures, but nowhere teaches or suggests an invention where the specific identity of some mass spectral components is not known, where the specific identity of more than 15 markers is not known, and where a computer system identifies the differences in case and control samples from blood samples of patients, using said more than 15 unidentified markers.

Chambers also cannot cure these deficiencies and in fact teaches away from the invention of amended claim 1. A reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. MPEP 2141.02.

Response to Office Communication dated April 19, 2005

According to the Office, Chambers indicates that "any mass spectral component identified by Olek et al. necessarily was first obtained without regards to the specific identity of at least some of the marker since all markers had to be identified after the acquisition of the data." Action at pages 5-6 (emphasis added). Applicants agree with the Office's characterization (italicized above) of Olek/Chambers, in that the Olek reference requires marker identification, so that all markers had to be identified. This teaches away from the invention as recited in amended claim 1, where a computer system identifies the differences in case and control samples from blood samples of patients, using more than 15 unidentified markers.

As the Office further points out, Chambers provides that in circumstances where proteins have incomplete sequence information, "it is necessary to obtain sequence information for the protein." Action at page 6. Rather than using unidentified markers in later steps, e.g., as recited in amended claim 1, Chambers teaches having to identify the protein for any further use. For example, Chambers continues, "[t]his sequence information can then be used along with the mass spectrometry information to interrogate expressed sequence tag (EST) databases." Chambers, page 283, right column (emphasis added). This teaches against using unidentified markers in accordance with amended claim 1, e.g., using unidentified markers in identifying the differences in case and control samples from blood samples of patients.

During the interview, the Examiner expressed concern that in the references the markers were at <u>some</u> point not known. The claim amendments herein clarify that the non-identified markers are not known when used in conjunction with a blood sample from a patient.

As neither Olek, Chambers nor Fouillet teaches or suggest certain limitations of amended claim 1, no combination of these references can provide each and every limitation of the claim. Thus, at least for this reason, Applicants respectfully request reconsideration and withdrawal of the obviousness rejection directed at claim 1.

Obvious rejection of claims 3, 7-10, 14, 15, 17-20, 22-27, 29-31, 38, 41 and 42 should be withdrawn as the Olek-Chambers-Fouillet references fail to teach or suggest at least 3 limitations of the claim 1, from which the claims depend

With respect to claims 3, 7-10, 14, 15, 17-20, 22-27, 29-31, 38, 41 and 42, Applicants respectfully submit that the obviousness rejections should be withdrawn as the Olek-Chambers-Fouillet references fail to teach or suggest certain limitations of claim 1, from

Response to Office Communication dated April 19, 2005

which each of the claims depend either directly (3, 7, 14, 15, 22-25, 29-31, 38 and 42) or indirectly (8-10, 17-20, 26, 27 and 41).

To reiterate, as neither Olek, nor Chambers, nor Fouillet teaches or suggests certain limitations of independent claim 1, no combination of these references can provide each and every limitation of claim 1, as required for a prima facie case of obviousness. As claims 3, 7-10, 14-15, 17-20, 22-27, 29-31, 38, 41 and 42 each depend from claim 1, they also cannot be rendered obvious by any combination of Olek, Chambers and Fouillet. Accordingly, for at least this reason, Applicants respectfully request reconsideration and withdrawal of the 103(a) rejections directed at claims 3, 7-10, 14, 15, 17-20, 22-27, 29-31, 38, 41, and 42.

Finally, Applicants do not address the Office's further arguments applying certain disclosures of Olek, Chambers and/or Fouillet to other elements and limitations of the claims. However, in doing so, Applicants in no way acquiesce to any of the Office's contentions.

·May 16. 2005 3:49PM WILSON SONSINI

No.5599 P. 12

Appl. No.: 10/645,863

Response to Office Communication dated April 19, 2005

## **CONCLUSION**

Applicants submit that the instant application is in condition for allowance and earnestly and respectfully request allowance of the now pending claims under examination. Should the Examiner have any questions, the Examiner is invited and encouraged to contact the undersigned attorney at the direct number provided.

The Commissioner is authorized to charge any fees that may be required in connection with this submission, including petition fees and extension of time fees, and to credit any overpayments to Deposit Account No. 23-2415 (Attorney Docket No. 29191-707.201).

WILSON SONSINI GOODRICH & ROSATI

Respectfully submitted,

Date: 5/16/05

Nicole M. Fortuné

Registration No. 52,905

650 Page Mill Road Palo Alto, CA 94304-1505 Phone: (650) 493-9300

Direct: (650) 849-3253 Client No. 021971